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David L. Fox
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1301 McKinney
Suite 5100
Houston TX 77010-3095

JAN 29 2008

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,167,242

NOTICE OF FINAL DETERMINATION-INELIGIBLE

Pfizer Health AB ("Applicant"), the present owner of record of U.S. Patent No. 5,167,242 ("the '242 patent"), through the previous patent owner of record, Pharmacia & Upjohn, filed an application ("PTE Application") for extension of the term of the '242 patent under 35 U.S.C. § 156 in the United States Patent and Trademark Office ("USPTO") on November 21, 1997. Applicant sought extension based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") of a human drug product known by the tradename NICOTROL® having the active ingredient nicotine. The Food and Drug Administration ("FDA") approved NICOTROL® for commercial use and sale on May 2, 1997.

A determination has been made that U.S. Patent No. 5,167,242 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of NICOTROL®.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The FDA official records indicate that nicotine was previously approved for commercial marketing or use prior to the approval of NICOTROL®. In a letter dated December 14, 1998, FDA stated:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd. 894 F. 2d 392 (Fed. Cir. 1990).

(Emphasis added).

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.

(Emphasis added).

Thus, the determination of eligibility of U.S. Patent No. 5,167,242 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(Emphasis added).

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredient in the approved product NICOTROL®, is nicotine. The USPTO uncovered that nicotine, the active ingredient of NICOTROL®, had been approved for commercial marketing and use prior to the approval of the applicant's product. Specifically, the FDA approved NDA No. 020385 on March 22, 1996, NDA No. 020536 on July 3, 1996 and NDA No. 020165 on August 2, 1996, the active ingredient of each NDA is nicotine (see attached printout from January 16, 2008 of a "Detail Record Search" for "nicotine" from the FDA's Electronic Orange Book). Each NDA approval was under section 505 of the FFDCA, the same provision of law under which regulatory review of the product NICOTROL® occurred. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's product, NICOTROL®, does not qualify as the first permitted marketing or use of the active ingredient. Since the approval of NICOTROL® was not the first permitted marketing or use of the active ingredient thereof, nicotine, the patent is not eligible for patent term extension based upon the regulatory review of NICOTROL® (nicotine). See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

Furthermore, Applicant failed to timely file the PTE Application. The December 14, 1998, letter from FDA confirms that NDA No. 20-714 for NICOTROL® was approved on May 2, 1997. Moreover, Applicant was clearly apprised of the approval date in the letter from FDA dated May 2, 1997, where FDA's letter states, in the fourth paragraph, "[a]ccordingly, the application is

approved effective on the date of this letter." A copy of this letter, as submitted with Applicant's PTE Application, is attached hereto. Since the approval date for NICOTROL® was May 2, 1997, the last date for submitting the PTE Application would have been June 30, 1997. As Applicant submitted the PTE Application on November 21, 1997, the application must be dismissed as untimely.

In sum, since Applicant failed to comply with 35 U.S.C. § 156(a)(5)(A) as NICOTROL® does not constitute the first permitted commercial marketing or use of the active ingredient nicotine, and Applicant failed to comply with 35 U.S.C. § 156(d)(1) as the PTE Application was untimely submitted, the PTE Application for NICOTROL® is **dismissed**.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: NICOTROL® (nicotine)
FDA Docket No.: 98E-0756

Search results from the "OB_Disc" table for query on "020536."

Active Ingredient:	NICOTINE
Dosage Form;Route:	FILM, EXTENDED RELEASE; TRANSDERMAL
Proprietary Name:	NICOTROL
Applicant:	MCNEIL CONS
Strength:	15MG/16HR
Application Number:	020536
Product Number:	001
Approval Date:	Jul 3, 1996
RX/OTC/DISCN:	DISCN

Patent and Exclusivity Info for this product: View

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through December, 2007
Patent and Generic Drug Product Data Last Updated: January 15, 2008

Search results from the "OB_Rx" table for query on "020385."

Active Ingredient:	NICOTINE
Dosage Form;Route:	SPRAY, METERED; NASAL
Proprietary Name:	NICOTROL
Applicant:	PFIZER INC
Strength:	0.5MG/SPRAY
Application Number:	020385
Product Number:	001
Approval Date:	Mar 22, 1996
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	

Patent and Exclusivity Info for this product: View

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Search results from the "OB_OTC" table for query on "020165."

Active Ingredient:	NICOTINE
Dosage Form;Route:	FILM, EXTENDED RELEASE; TRANSDERMAL
Proprietary Name:	NICODERM CQ
Applicant:	SANOFI AVENTIS US
Strength:	21MG/24HR
Application Number:	020165
Product Number:	004
Approval Date:	Aug 2, 1996
Reference Listed Drug	Yes
RX/OTC/DISCN:	OTC
Patent and Exclusivity Info for this product:	View

Active Ingredient:	NICOTINE
Dosage Form;Route:	FILM, EXTENDED RELEASE; TRANSDERMAL
Proprietary Name:	NICODERM CQ
Applicant:	SANOFI AVENTIS US
Strength:	14MG/24HR
Application Number:	020165
Product Number:	005
Approval Date:	Aug 2, 1996
Reference Listed Drug	Yes
RX/OTC/DISCN:	OTC
Patent and Exclusivity Info for this product:	View

Active Ingredient:	NICOTINE
Dosage Form;Route:	FILM, EXTENDED RELEASE; TRANSDERMAL
Proprietary Name:	NICODERM CQ
Applicant:	SANOFI AVENTIS US
Strength:	7MG/24HR
Application Number:	020165
Product Number:	006
Approval Date:	Aug 2, 1996
Reference Listed Drug	Yes
RX/OTC/DISCN:	OTC
Patent and Exclusivity Info for this product:	View

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-714

MAY 2 1997

Pharmacia and Upjohn Company
7000 Portage Road
Kalamazoo, Michigan 49001

Attention: Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

Dear Dr. Dann:

Please refer to your new drug application (NDA) dated May 1, 1996, received May 2, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicotrol Inhaler (nicotine inhalation system), 10 mg/cartridge (4 mg delivered).

We acknowledge receipt of your submissions dated June 5, June 7, June 24, September 6, November 6, and December 5, 1996; January 13, January 29, March 7, March 20, March 24, March 26, April 7, April 15, April 24, April 29, April 30 and May 1, 1997. The User Fee goal date for this application is May 2, 1997.

This new drug application provides for a new nicotine replacement product as an aid to smoking cessation.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed marked-up draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-714. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submission dated May 1, 1997. These commitments, along with any completion dates agreed upon, are listed below.

1. To modify the Inhaler mouthpiece and/or the product packaging to minimize the risk of pediatric poisoning from accidental ingestion, within 6-12 months after approval.

2. To track pediatric exposure to the Nicotrol Inhaler as reported to the American Association of Poison Control Centers.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Bonnie McNeal, Project Manager, at (301) 443-3741.

Sincerely,

Curtis Wright, M.D., M.P.H.
Acting Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE